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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,269	03/17/2004	Hideji Tajima	10287.62	4205

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EXAMINER	
REIFSNYDER, DAVID A	

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/802,269	TAJIMA, HIDEJI	
	Examiner	Art Unit	
	David A. Reifsnyder	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-14* is/are rejected.

7)☒ Claim(s) *2* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/898,762.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 3; the recitation of "storing the first suspension to a storage section" is vague and indefinite as to what is meant by "to a storage section". Should "to a storage section" be ---in a storage section---?

Regarding claim 4; the recitation of "from a second container" does not make sense because a first container was never claimed. Furthermore, it is vague and indefinite as to what structure of the pipette apparatus sucks the liquid from a second container. In addition, it is vague and indefinite as to how the" second liquid passage" is structurally related to the "first liquid passage", and it is vague and indefinite as to how the "first liquid passage" is structurally related to the pipette apparatus. Furthermore, the recitation of "discharging the liquid" is vague and indefinite as to what structure the liquid is discharged into. (i.e. the liquid must be discharged to some structure, or else the "eluting the target substance from the magnetic particles in the second suspension" as claimed in claim 1 could not occur) Lastly, because of the 35

USC 112 2nd paragraph problems with claim 4, the entire claim 4 can not be understood.

Regarding claim 5; the recitation of "from a second container" is vague and indefinite as to whether that second container is the same second container as the second container claimed in claim 2. Furthermore, the recitation of "by sucking the liquid from a second container, storing the liquid, passing the liquid through the first discharge passage" is vague and indefinite, because "sucking the liquid from a second container, storing the liquid, passing the liquid through the first discharge passage" was already claimed in claim 2. Furthermore, it is vague and indefinite as to what structure of the pipette apparatus sucks the liquid from a second container. In addition, it is vague and indefinite as to how the" second liquid passage" is structurally related to the "first liquid passage", and it is vague and indefinite as to how the "first liquid passage" is structurally related to the pipette apparatus. In addition, the recitation of "discharging the liquid" is vague and indefinite as to what structure the liquid is discharged into. (i.e. the liquid must be discharged in to some structure, or else the "eluting the target substance from the magnetic particles in the second suspension" as claimed in claim 1 could not occur) Lastly, the recitation of "discharging the liquid" is also vague and indefinite because claim 2 claims, "discharging the suspension into the second container", and the suspension and the liquid are the same thing. Lastly, because of the 35 USC 112 2nd paragraph problems with claim 5, the entire claim 5 can not be understood.

Regarding claim 6; the recitation of "from a second container" is vague and indefinite as to whether that second container is the same second container as the second container claimed in claim 3. Furthermore, it is vague and indefinite as to what structure of the pipette apparatus sucks the liquid from a second container. In addition, it is vague and indefinite as to how the" second liquid passage" is structurally related to the "first liquid passage", and it is vague and indefinite as to how the "first liquid passage" is structurally related to the pipette apparatus. Furthermore, the recitation of "by sucking the liquid from a second container, storing the liquid, passing the liquid through the first discharge passage" is vague and indefinite, because "sucking the liquid from a second container, passing the liquid through the first discharge passage" was claimed in claim 3. In addition, the recitation of "discharging the liquid" is vague and indefinite as to what structure the liquid is discharged into. (i.e. the liquid must be discharged in to some structure, or else the "eluting the target substance from the magnetic particles in the second suspension" as claimed in claim 1 could not occur) Lastly, the recitation of "discharging the liquid" is also vague and indefinite because claim 3 claims, "discharging the liquid into the second container". Lastly, because of the 35 USC 112 2nd paragraph problems with claim 6, the entire claim 6 can not be understood.

Regarding claim 7; the recitation of "the magnetic particles are separated" is vague and indefinite as to what the magnetic particles are separated from. (i.e. are the magnetic particles separated from the first suspension?) Furthermore, the recitation of "shifting the liquid stored in a second container to a first container, after the suspension

stored in the first container is shifted to the second container" does not make sense because the storing of the liquid in a second container, and the storing of the suspension in a first container, was never claimed. Furthermore, the recitation of "the suspension" lacks antecedent basis, because it is vague and indefinite as to whether "the suspension" is ---the first suspension--- or ---the second suspension---. Lastly, because of the 35 USC 112 2nd paragraph problems with claim 7, the entire claim 7 can not be understood.

Regarding claim 8; the recitation of "the magnetic particles are separated" is vague and indefinite as to what the magnetic particles are separated from. (i.e. are the magnetic particles separated from the first suspension?) Furthermore, the recitation of "shifting the liquid stored in the second container to the first container, after the suspension stored in the first container is shifted to the second container" does not make sense because the storing of the liquid in a second container, and the storing of the suspension in a first container, was never claimed. Claim 2 does claim "sucking the liquid from a second container"; however, that is not clearly the same as ---sucking the liquid from a second container in which the liquid is stored". Also, the recitation of "the suspension stored in the first container" lacks antecedent basis, because it is vague and indefinite as to whether "the suspension" is ---the first suspension--- or ---the second suspension---. Lastly, because of the 35 USC 112 2nd paragraph problems with claim 8, the entire claim 8 can not be understood.

Regarding claim 9; the recitation of "the magnetic particles are separated" is vague and indefinite as to what the magnetic particles are separated from. (i.e. are the

magnetic particles separated from the first suspension?) Furthermore, the recitation of "shifting the liquid stored in the second container to the first container, after the suspension stored in the first container is shifted to the second container" does not make sense because the storing the suspension in the first container, was never claimed. One other thing, the recitation of "the suspension stored in the first container" lacks antecedent basis, because it is vague and indefinite as to whether "the suspension" is ---the first suspension--- or ---the second suspension---. Lastly, because of the 35 USC 112 2nd paragraph problems with claim 9, the entire claim 9 can not be understood.

Regarding claim 10; the recitation of "the magnetic particles are separated" is vague and indefinite as to what the magnetic particles are separated from. (i.e. are the magnetic particles separated from the liquid?) ?) Furthermore, the recitation of "shifting the liquid stored in the second container to the first container, after the suspension stored in the first container is shifted to the second container" does not make sense because the storing of the liquid in a second container, and the storing of the suspension in a first container, was never claimed. Claim 4 does claim "sucking the liquid from a second container"; however, that is not clearly the same as ---sucking the liquid from a second container in which the liquid is stored". One other thing, the recitation of "the suspension stored in the first container" lacks antecedent basis, because it is vague and indefinite as to whether "the suspension" is ---the first suspension--- or ---the second suspension---. Lastly, because of the 35 USC 112 2nd paragraph problems with claim 10, the entire claim 10 can not be understood.

Regarding claim 11; the recitation of "the magnetic particles are separated" is vague and indefinite as to what the magnetic particles are separated from. (i.e. are the magnetic particles separated from the first suspension?) Furthermore, the recitation of "shifting the liquid stored in a second container to a first container, after the suspension stored in the first container is shifted to the second container" does not make sense because the storing of the liquid in a second container, and the storing of the suspension in a first container, was never claimed. Furthermore, the recitation of "the suspension" lacks antecedent basis, because it is vague and indefinite as to whether "the suspension" is ---the first suspension--- or ---the second suspension---. Lastly, because of the 35 USC 112 2nd paragraph problems with claim 11 the entire claim 11 can not be understood.

Regarding claim 12; the recitation of "the magnetic particles are separated" is vague and indefinite as to what the magnetic particles are separated from. (i.e. are the magnetic particles separated from the first suspension?) Furthermore, the recitation of "shifting the liquid stored in the second container to the first container, after the suspension stored in the first container is shifted to the second container" does not make sense because the storing of the liquid in a second container, and the storing of the suspension in a first container, was never claimed. Claim 2 does claim "sucking the liquid from a second container"; however, that is not clearly the same as ---sucking the liquid from a second container in which the liquid is stored". Also, the recitation of "the suspension stored in the first container" lacks antecedent basis, because it is vague and indefinite as to whether "the suspension" is ---the first suspension--- or ---

the second suspension---. Lastly, because of the 35 USC 112 2nd paragraph problems with claim 12, the entire claim 12 can not be understood.

Regarding claim 13; the recitation of "the magnetic particles are separated" is vague and indefinite as to what the magnetic particles are separated from. (i.e. are the magnetic particles separated from the first suspension?) Furthermore, the recitation of "shifting the liquid stored in the second container to the first container, after the suspension stored in the first container is shifted to the second container" does not make sense because the storing the suspension in the first container, was never claimed. One other thing, the recitation of "the suspension stored in the first container" lacks antecedent basis, because it is vague and indefinite as to whether "the suspension" is ---the first suspension--- or ---the second suspension---. Lastly, because of the 35 USC 112 2nd paragraph problems with claim 13, the entire claim 13 can not be understood.

Regarding claim 14; the recitation of "the magnetic particles are separated" is vague and indefinite as to what the magnetic particles are separated from. (i.e. are the magnetic particles separated from the liquid?) ?) Furthermore, the recitation of "shifting the liquid stored in the second container to the first container, after the suspension stored in the first container is shifted to the second container" does not make sense because the storing of the liquid in a second container, and the storing of the suspension in a first container, was never claimed. Claim 4 does claim "sucking the liquid from a second container"; however, that is not clearly the same as ---sucking the liquid from a second container in which the liquid is stored". One other thing, the

recitation of "the suspension stored in the first container" lacks antecedent basis, because it is vague and indefinite as to whether "the suspension" is ---the first suspension--- or ---the second suspension---. Lastly, because of the 35 USC 112 2nd paragraph problems with claim 14, the entire claim 14 can not be understood.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4, 7,10, 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forest et al. in view of WO 98/31840.

Regarding claims 1, 4, 7,10, 11 and 14; Forrest et al. discloses a method using magnetic particles comprising:

capturing a target biological material in a first suspension having a first volume with magnetic particles; (col. 1, lines 61-63; claim 23 step a)

separating the magnetic particles from the first suspension by passing the first suspension through a first liquid passage and exerting a magnetic field from outside the first liquid passage to inside the first liquid passage to thereby attract the magnetic particles to an inner wall of the first liquid passage (col. 1, lines 64-68; claim 23, steps b-c); and

suspending the magnetic particles in a liquid having a second volume to obtain a second suspension, by passing the liquid through the first liquid passage without exerting a magnetic field on the first liquid passage (col. 3, lines 49-64; claims 25-26).

Furthermore, Forrest et al. discloses sample receptacles 16 (i.e. suspension containers), a wash receptacle 16 (i.e. a liquid container); and a peristaltic-type pump (i.e. a pipette apparatus).

Regarding claims 1, 4, 7,10, 11 and 14; Forrest et al. fails to disclose that the second volume is less than the first volume, and Forrest et al. also fails to disclose the step of eluting the target substance from the magnetic particles in the second suspension. Regarding the limitation that the second volume is less than the first volume; Forrest et al. discloses a method for determining a constituent of interest (i.e. the target biological material) in a sample (i.e. suspension) by analysis of the separated solid phase (col. 2, lines 1-3; claim 23 step d). To have more of the target biological material and less of the liquid, which is not of interest;it is considered that it would have been obvious to one having ordinary skill in the art at the time of the invention, for Forrest et al.'s second volume be less then his first volume.

Regarding claims 1, 4, 7,10, 11 and 14; Forrest et al. **suggests** the instantly claimed method except for the step of eluting the target substance from the magnetic particles in the second suspension.

Regarding claims 1, 4, 7,10, 11 and 14; WO 98/31840 discloses a method using silica magnetic particles comprising:

capturing a target biological material in a suspension with the silica magnetic particles, thereby forming a complex of magnetic silica particles and the biological target material;

separating the complex from the suspension using external magnetic force;

and

eluting the biological target material from the complex. (i.e. eluting the biological target material from the silica magnetic particles) (see the abstract) I

It is considered that it would have been obvious to one having ordinary skill in the art at the time of the invention for Forrest et al. to elute the target biological from the magnetic particles as taught by WO 98/31840, in order for Forrest et al. to be able to better analyze his targeted biological material. (see col. 2, lines 1-3 of Forrest et al.)

Response to Arguments

Applicant's arguments on page 10, lines 7-16 of his remarks, filed May 16, 2005, with respect to the 35 USC 103 rejection of claim 1 over Sumiya' 687 (i.e. JP 10-332687) have been fully considered and are **not** persuasive. However, the applicant's arguments on page 11, line 19 to page 12 line 5 of his remarks, filed May 16, 2005, with

respect to the 35 USC 103 rejection of claim 1 over Sumiya' 687 (i.e. JP 10-332687) have been fully considered and **are** persuasive. The 35 USC 103 rejection of claim 1 over JP 10-32687 **has been withdrawn.**

Applicant's arguments on page 12, lines 6-19 of his remarks, filed May 16, 2005, with respect to the 35 USC 103 rejection of claim 1 over Tajima' 602 (i.e. WO 96/29602) have been fully considered and **are** persuasive. Furthermore, page 12, lines 15-18 states that "Tajima'602 does not disclose or suggest re-suspending the magnetic particles in a second liquid after the magnetic particles have been separated from a suspension in which the second liquid has a smaller volume then the first suspension". It is noted that the applicant incorrectly states **re-suspending** the magnetic particles, and the applicant also incorrect states that the liquid is a **second** liquid. The applicants statement on page 12 lines 15-18 should have been: ---Tajima'602 does not disclose or suggest **suspending** the magnetic particles in a **liquid** after the magnetic particles have been separated from a suspension in which the **liquid** has a smaller volume then the first suspension---. Furthermore, while it is true that Tajima'602 does not disclose or suggest suspending the magnetic particles in a liquid after the magnetic particles have been separated from a suspension in which the liquid has a smaller volume then the first suspension; it is noted that Tajima' 602 **does not disclose or suggest suspending the magnetic particles in a liquid at all.** The 35 USC 103 rejection of claim 1 over Tajima **has been withdrawn.**

Lastly, the applicant's arguments, filed May 16, 2005 are **moot** in view of the **new ground of rejection.**

Allowable Subject Matter

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 3, 5, 6, 8, 9, 12 and 13 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The main reason for the allowance of claims 2, 5, 8 and 12 over art is that the prior art of record fails to describe or fairly suggest the instantly claimed method as a whole and including wherein the magnetic particles are separated from the first suspension by sucking the first suspension from a first container **storing the first suspension**, and then passing the first suspension through the first liquid passage; and the magnetic particles are suspended in the liquid to create the second suspension by sucking the liquid from a second container, **storing the liquid**, passing the liquid through the first passage and **discharging the second suspension into the second container.**

The main reason for the allowance of claims 3, 6, 9 and 13 over art is that the prior art of record fails to describe or fairly suggest the instantly claimed method as a whole and including wherein **the first liquid passage includes a suction portion and a discharge portion, and wherein, the magnetic particles are separated from the first suspension by sucking the first suspension from a first container storing the first suspension to a storage section associated with the suction portion of the**

first liquid passage while exerting the magnetic field from outside the suction portion and the discharge portion of the first liquid passage, and discharging the first suspension from the storage section through the discharge portion of the first liquid passage, to thereby attract the magnetic particles to the inner wall of the suction portion and the discharge portion of the first liquid passage; and the magnetic particles are suspended in the liquid by inserting the suction portion and the discharge portion of the first liquid passage into a second container in which the liquid having a second volume is stored, wherein the second volume is substantially the same as the volume of the storage section and then sucking the liquid from the second container, passing the liquid through the first liquid passage and discharging the liquid into the second container, without exerting a magnetic field on the first liquid passage.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Smith et al. who discloses methods of isolating biological target materials using silica magnetic particles.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Reifsnyder whose telephone number is (571) 272-1145. The examiner can normally be reached on M-F 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda M. Walker can be reached on (571) 272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A Reifsnyder
Primary Examiner
Art Unit 1723

DAR